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L6: Entry 2 of 14

File: USPT

Aug 7, 2001

DOCUMENT-IDENTIFIER: US 6270790 B1

TITLE: Soft, convex shaped chewable tablets having reduced friability

Detailed Description Text (6):

The tablets of the present invention are used to orally administer a wide variety of active ingredients. Suitable active ingredients include pharmaceuticals, minerals, vitamins and other nutraceuticals. Suitable pharmaceuticals include analgesics, decongestants, expectorants, antitussives, antihistamines, gastrointestinal agents, diuretics, bronchodilators, sleep-inducing agents and mixtures thereof. Preferred pharmaceuticals include acetaminophen, ibuprofen, flurbiprofen, naproxen, aspirin, pseudoephedrine, phenylpropanolamine, chlorpheniramine maleate, dextromethorphan, diphenhydramine, famotidine, loperamide, ranitidine, cimetidine, astemizole, terfenadine, terfenadine carboxylate, cetirizine, mixtures thereof and pharmaceutically acceptable salts thereof.

Detailed Description Text (17):

The coated particle, in a dried state, generally contains about 5 to about 60, preferably about 10 to 40, weight percent of the blend of the first and second polymers. The exact proportions of the coating to the active ingredient can, however, vary depending upon the level of taste masking required and whether a sustained or immediate release of the active is desired. Larger proportions of the coating tend to provide a sustained release effect and enhance taste masking.

Other Reference Publication (2):

Danckwerts et al., The Effect of Processing Variables in the Compression Properties of Controlled Release Core-In-Cup Compressed Tablets from a New Adjustable Punch, International Journal of Pharmaceutics, 123 pp. 85-94, 1995.*

CLAIMS:

8. The tablet of claim 1 wherein the active ingredient is selected from the group consisting of acetaminophen, ibuprofen, flurbiprofen, naproxen, aspirin, pseudoephedrine, phenylpropanolamine, chlorpheniramine maleate, dextromethorphan, diphenhydramine, famotidine, loperamide, ranitidine, cimetidine, astemizole, terfenadine, terfenadine carboxylate, cetirizine, mixtures thereof and pharmaceutically acceptable salts thereof.

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DATE-ISSUED: August 7, 2001

INVENTOR-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY
Robinson; Ronni L.	Ambler	PA		
Damon; James R.	Chalfont	PA		
Mossop; James R.	Quakertown	PA		
Palmer; Michael D.	Philadelphia	PA		

US-CL-CURRENT: 424/441; 424/439, 424/489, 424/490, 424/493, 424/494, 424/497

CLAIMS:

What is claimed is:

1. A compressed, chewable tablet having opposed major surfaces, comprising:

about 0.1 to about 60% of at least one active ingredient coated with a taste masking coating;

about 30 to about 90% of a water-disintegratable, compressible carbohydrate selected from the group consisting of mannitol, sorbitol, maltitol, dextrose, sucrose, xylitol, lactose, and mixtures thereof;

about 1 to about 30% of a binder selected from the group consisting of cellulose, cellulosic derivatives, polyvinyl pyrrolidone, starch, modified starch and mixtures thereof;

about 0.1 to about 5% of a lubricant;

0 to about 5% sweetener;

0 to about 5% flavor;

0 to about 5% color, by weight of said tablet; and

said face surfaces having a convex shape and said tablet having a hardness of about 2 to about 11 kp/cm.^{sup.2} and a friability of less than about 1%.

2. The tablet of claim 1 having a hardness of about 5 to about 8.5 kp/cm.^{sup.2}.

3. The tablet of claim 1 having a friability of less than about 0.5%.

4. The tablet of claim 1 wherein said face surfaces have a bi-convex or tri-convex shape.

5. The tablet of claim 4 having bi-convex shaped face surfaces and a minor axis cup radius of about 10 to about 40 percent of the tablet diameter and major axis cup radius of about 100 to about 400 percent of the tablet diameter.

6. The tablet of claim 1 wherein said coated active ingredient comprises at least one active ingredient coated with a blend of a first polymer selected from the group consisting of a cellulose acetate and cellulose acetate butyrate and a second polymer selected from the group consisting of polyvinyl pyrrolidone and hydroxypropyl cellulose, wherein the weight ratio of the first polymer to the second polymer is within the range of about 90:10 to about 50:50.

7. The tablet of claim 6 wherein the coated active ingredient comprises about 5 to about 60 percent by weight of the blend of first and second polymers.

8. The tablet of claim 1 wherein the active ingredient is selected from the group consisting of acetaminophen, ibuprofen, flurbiprofen, naproxen, aspirin, pseudoephedrine, phenylpropanolamine, chlorpheniramine maleate, dextromethorphan, diphenhydramine, famotidine, loperamide, ranitidine, cimetidine, astemizole, terfenadine, terfenadine carboxylate, cetirizine, mixtures thereof and pharmaceutically acceptable salts thereof.

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Palmer; Michael D.	Philadelphia	PA		

ASSIGNEE-INFORMATION:

NAME	CITY	STATE	ZIP CODE	COUNTRY	TYPE CODE
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APPL-NO: 09/ 135723 [PALM]

DATE FILED: August 18, 1998

INT-CL: [07] A61 K 9/28, A61 K 47/00

US-CL-ISSUED: 424/441; 424/439, 424/489, 424/490, 424/493, 424/494, 424/497

US-CL-CURRENT: 424/441; 424/439, 424/489, 424/490, 424/493, 424/494, 424/497

FIELD-OF-SEARCH: 424/464, 424/465, 424/494, 424/482, 424/470, 424/439, 424/441, 424/489, 424/490, 424/493, 424/497

PRIOR-ART-DISCLOSED:

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<input type="checkbox"/>	<u>4851226</u>	July 1989	Julian et al.	
<input type="checkbox"/>	<u>5075114</u>	December 1991	Roche	424/470
<input type="checkbox"/>	<u>5275823</u>	January 1994	France et al.	
<input type="checkbox"/>	<u>5460825</u>	October 1995	Roche et al.	
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<input type="checkbox"/>	<u>5609883</u>	March 1997	Valentine et al.	424/464
<input type="checkbox"/>	<u>5686107</u>	November 1997	Ratnaraj et al.	
<input type="checkbox"/>	<u>5876759</u>	March 1999	Gowan, Jr.	424/494

FOREIGN PATENT DOCUMENTS

FOREIGN-PAT-NO	PUBN-DATE	COUNTRY	US-CL
98/46215	October 1998	WO	

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Muresan et al., Stability Study if Pyroxicam in the Presence of Auxiliary Substances of Compression, Farmacia 41, No. 1-2, pp. 51-56, 1993.*

Danckwerts et al., The Effect of Processing Variables in the Compression Properties of Controlled Release Core-In-Cup Compressed Tablets from a New Adjustable Punch, International Journal of Pharmaceutics, 123 pp. 85-94, 1995.*

Westerhuis et al., Optimisation of the Composition and Production of Mannitol/Microcrystalline Cellulose Tablets, International Journal of Pharmaceutics, 143 pp. 151-162, 1996.*

Muntean et al., Formulation and Preparation of Some Chewable Tablets for Local Treatment of Bucco-Pharyngeal Infections, Farmacia 41, No. 1-2, pp. 51-56, 1993.*

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Aulton, M.E., Pharm. Helv. vol. 56, No. 12, p. 332-6 (1981).

Hwang et al. Drug Development and Industrial Pharmacy, vol. 19, No. 5, p. 507-19 (1973).

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Kigasawa et al. Yakugaku Zasshi, vol. 95, No. 7, p. 769-773 (1975).

ART-UNIT: 165

PRIMARY-EXAMINER: Page; Thurman K.

ASSISTANT-EXAMINER: Seidleck; Brian K.

ABSTRACT:

The present invention relates to a compressed, chewable tablet containing at least one active ingredient, a water-disintegratable, compressible carbohydrate and a binder. These components are dry blended and compressed into convex-shaped tablet having a hardness of about 2 to about 11 kp/cm.^{sup.2} and friability less than 1%.

8 Claims, 3 Drawing figures

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CONTROLLED.DWPI,TDBD,EPAB,JPAB,USPT.	1875210
COMPRESSION.DWPI,TDBD,EPAB,JPAB,USPT.	540029
COATING.DWPI,TDBD,EPAB,JPAB,USPT.	1081085
LAYERED.DWPI,TDBD,EPAB,JPAB,USPT.	119477
TABLET.DWPI,TDBD,EPAB,JPAB,USPT.	75893
BILAYERED.DWPI,TDBD,EPAB,JPAB,USPT.	738
INNER.DWPI,TDBD,EPAB,JPAB,USPT.	1798670
(L3 AND (CETIRIZINE.CLM. OR PSEUDOEPHEDRINE.CLM. OR IMMEDIATE RELEASE OR CONTROLLED RELEASE OR COMPRESSION COATING OR LAYERED TABLET OR BILAYERED TABLET OR INNER CORE OR OUTER LAYER)).USPT,JPAB,EPAB,DWPI,TDBD.	59

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<u>L4</u>	l3 and (cetirizine.clm. or pseudoephedrine.clm. or immediate release or controlled release or compression coating or layered tablet or bilayered tablet or inner core or outer layer)	59	<u>L4</u>
<u>L3</u>	l1 and l2	72	<u>L3</u>
<u>L2</u>	pseudoephedrine	1053	<u>L2</u>
<u>L1</u>	cetirizine	257	<u>L1</u>

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<u>L4</u>	13 and (cetirizine.clm. or pseudoephedrine.clm. or immediate release or controlled release or compression coating or layered tablet or bilayered tablet or inner core or outer layer)	59	<u>L4</u>
<u>L3</u>	11 and 12	72	<u>L3</u>
<u>L2</u>	pseudoephedrine	1053	<u>L2</u>
<u>L1</u>	cetirizine	257	<u>L1</u>

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